REMARKS

Claims 1-4 and 17-32 were presented for examination and were rejected.

The applicants have added the recited limitations of claim 26 to claim 1. Accordingly, the applicants have canceled claim 26 without prejudice, and reserve the right to re-add the canceled claim to this or another application.

The applicants respectfully request reconsideration in light of the amendments and the following comments.

35 U.S.C. § 102 Rejection of Claims 1, 3, 4, 20-21, 24, 25, and 32

Claims 1, 3, 4, 20-21, 24, 25, and 32 were rejected under 35 U.S.C. § 102(b) as being anticipated by Brown et al, U.S. Patent 6,071,305 (hereinafter "Brown").

The applicants have amended claim 1 to incorporate the recited limitations of claim 26 (now canceled), and respectfully submit that the amendment to claim 1 overcomes the rejection.

Claim 1, as amended, recites:

> **1.** A drug delivery device comprising: a drug; and a vascular implant having a blood-contacting surface and a helical formation on the blood contacting surface, the *helical formation having a helix angle of between 8° and 20°* and being capable of inducing helical flow of blood flowing past the helical formation, and the drug being releasably associated with the helical formation of the vascular implant.
>
> (*emphasis supplied*)

Nowhere does Brown teach or suggest, alone or in combination with the other references, what amended claim 1 recites — namely a helical formation having a helix angle of between 8° and 20°.

For this reason, the applicants respectfully submit that the rejection of claim 1 is overcome.

Because claims 3, 4, 20-21, 24, 25, and 32 depend on claim 1, the applicants respectfully submit that the rejection of them is also overcome.

35 U.S.C. § 103 Rejection of Claims 1-4, 17-25, and 27-32

Claims 1-4, 17-25, and 27-32 were rejected under 35 U.S.C. § 103 as being unpatentable over Houston et al, U.S. Patent Publication No. 2003/0139807 (hereinafter

"Houston") in view of Falotico et al, U.S. Patent 7,195,640 (hereinafter "Falotico"). The applicants respectfully traverse the rejection.

Claim 1 recites:

> **1.** A drug delivery device comprising: a drug; and a vascular implant having a blood-contacting surface and a helical formation on the blood contacting surface, the helical formation having a helix angle of between 8° and 20° and being capable of inducing helical flow of blood flowing past the helical formation, and the drug being releasably associated with the helical formation of the vascular implant.

In section 1 on page 2 of the most recent Office action, the Examiner refers to the Declaration filed by the applicants under 37 CFR 1.132, in response to the previous Office action. The Declaration compared the elution of a drug (aspirin) from a spiral stent (in accordance with the present invention) with elution from a control stent. The Examiner argued that the Declaration was unclear because the spiral stent, prior to testing, accumulated "a heavier coating than the control, which may be due to the spiral. The heavier coating may be the result of the spiral coating having greater elution of the drug since there is more drug to elute and the drug is located within a spiral." The Examiner concludes that, "the results may not have been expected but would be obvious due to the heavier coating."

The Examiner is correct that the total load of aspirin present in the control stent in each run was heavier than that of the corresponding spiral stent (see section 6 of the Declaration). However, the applicants respectfully submit that the Examiner has misunderstood the results presented in the Declaration. More specifically, the Declaration also provides the results of absorption of aspirin present in the collection tank after every run (see section 6 of the Declaration) which provides a calculation of the "increase in absorption from spiral stent." In other words, these results give an indication of the elution of the drug (aspirin) during each run. It will noted that, except in the case of the third run, the portional increase in absorption from the spiral stent was much greater than the proportional increase in the load of aspirin on the spiral stent. The comparison is shown in the following table, which is a summary of the data presented in the Declaration.

Run	Increase of aspirin load on spiral stent	Increase in absorption from spiral stent
First	55.5%	69%
Second	60%	75%
Third	60%	59%
Fourth	50%	81%

As explained in section 12 of the Declaration, the third run was apparently anomalous. Therefore, reliable data on the runs indicate that the elution of the drug was increased to an extent greater than would have been expected merely due to the heavier coating of the spiral stent. As such, the applicants respectfully submit that the argument that they made previously still stands, namely that the provision of the helical formation on the blood contacting surface of the drug delivery device of the present invention allows elution of more of the drug than the device without the helical formation and the increase is at a level that would be unexpected, and that the results are non-obvious.

For these reasons, the applicants respectfully submit that the rejection of claim 1 is traversed.

Because claims 2-4, 17-25, and 27-32 depend on claim 1, the applicants respectfully submit that the rejection of them is also traversed.

35 U.S.C. 103 Rejection of Claim 26

Claim 26 has been rejected under 35 U.S.C. 103 as being unpatentable over Houston in view of Falotico, further in view of Houston et al, EP 1254645A1 (hereinafter "Houston '645").

The applicants point out that Houston '645 does not relate to drug delivery at all and provides no reason for a skilled person to have expected the technical benefit discussed above and with respect to claim 1. Because claim 26 is dependent upon claim 1 and because Houston '645 fails to cure the deficiencies of Houston and Falotico with respect to the rejection of claim 1, the applicants respectfully submit that the rejection of claim 26 is traversed as well.

35 U.S.C. 103 Rejection of Claim 2

Claim 2 has been rejected under 35 U.S.C. 103 as being unpatentable over Brown in view of Kaplan, U.S. Patent 5,342,348 (hereinafter "Kaplan"). Because claim 2 is

dependent upon claim 1 and because Kaplan fails to cure the deficiencies of Brown with respect to the rejection of claim 1, the applicants respectfully submit that the rejection of claim 2 is overcome as well.

35 U.S.C. 103 Rejection of Claims 17 and 18

Claims 17 and 18 have been rejected under 35 U.S.C. 103 as being unpatentable over Brown in view of Dutta et al, U.S. Patent 6,702,849 (hereinafter "Dutta"). Because claims 17 and 18 are dependent upon claim 1 and because Dutta fails to cure the deficiencies of Brown with respect to the rejection of claim 1, the applicants respectfully submit that the rejection of claims 17 and 18 is overcome as well.

35 U.S.C. 103 Rejection of Claim 19

Claim 19 has been rejected under 35 U.S.C. 103 as being unpatentable over Brown in view of Dutta as applied to claim 17 above, and further in view of Davila et al, U.S. Patent Publication No. 2002/0111590A1 (hereinafter "Davila"). Because claim 19 is dependent upon claim 1 and because Davila fails to cure the deficiencies of Brown and Dutta with respect to the rejection of claim 1, the applicants respectfully submit that the rejection of claim 19 is overcome as well.

35 U.S.C. 103 Rejection of Claims 22 and 23

Claims 22 and 23 been rejected under 35 U.S.C. 103 as being unpatentable over Brown in view of Banas et al, U.S. Patent 5,749, 880 (hereinafter "Banas"). Because claims 22 and 23 are dependent upon claim 1 and because Banas fails to cure the deficiencies of Brown with respect to the rejection of claim 1, the applicants respectfully submit that the rejection of claim 22 and 23 is overcome as well.

35 U.S.C. 103 Rejection of Claim 26

Claim 26 has been rejected under 35 U.S.C. 103 as being unpatentable over Brown.

The applicants have canceled claim 26, incorporating its recited limitations into claim 1. With regard to those claim 26 limitations now incorporated into claim 1, on page 10 of the Office action, the Examiner has acknowledged that Brown does not disclose "a helical formation having a helix angle between 8° and 20°." The applicants agree with this.

The Examiner goes on to state that "it would have been an obvious matter of design choice to have provided a helical formation having a helix angle at between 8° and 20° since the applicant has not disclosed that an angle between 8° and 20° [...] is for any particular purpose and it appears that the invention would perform equally well with a helix angle appropriate for the size of the stent used for the particular application."

The applicants completely disagree with this statement. On page 10, lines 13-16 of the present application (see the published PCT application) it is explained that the helix angle of between 8° and 20° induces helical blood flow. Therefore, the selection of this range of helix angles is not "an obvious matter of design choice" since it is not purely arbitrary. On the contrary, the range of helix angles does have a distinct technical effect. The reason that the stent of Brown is helical is never stated in the reference, but it is stated that "the stent 11 functions both to physically support the body lumen wall and also to prevent restenosis and thrombosis" (see column 7, lines 56-59 of Brown). This implies that the helix angle of the helical stent must be relatively high in order to provide the structural integrity required to support the body lumen. Accordingly, it would be completely counter-intuitive to a skilled person to lower the helix angle of the helical stent of Brown to the range between 8° and 20°. Therefore, amended claim 1 is non-obvious with respect to Brown.

Because of these reasons, and because the applicants have canceled claim 26, the applicants respectfully submit that the rejection of claim 26 has been addressed.

35 U.S.C. 103 Rejection of Claims 27-31

Claims 27-31 have been rejected under 35 U.S.C. 103 as being unpatentable over Brown in view of Stinson, U.S. Patent Publication No. 2004/0044397A1 (hereinafter "Stinson"). Because claims 27-31 are dependent upon claim 1 and because Stinson fails to cure the deficiencies of Brown with respect to the rejection of claim 1, the applicants respectfully submit that the rejection of claims 27-31 is overcome as well.

Request for Reconsideration Pursuant to 37 C.F.R. 1.111

Having responded to each and every ground for objection and rejection in the last Office action, applicants respectfully request reconsideration of the instant application pursuant to 37 CFR 1.111 and request that the Examiner allow all of the pending claims and pass the application to issue.

If there are remaining issues, the applicants respectfully request that Examiner telephone the applicants' attorney so that those issues can be resolved as quickly as possible.

Respectfully,
Robert Gordon Hood et al.

By **/Kenneth Ottesen/**
Kenneth Ottesen
Reg. No. 54353
732-578-0103 x222

DeMont & Breyer, L.L.C.
Suite 250
100 Commons Way
Holmdel, NJ 07733
United States of America